VIA ELECTRONIC DELIVERY

October 26, 2018

Ms. Susan Edwards
Office of Inspector General
Department of Health and Human Services
Attn: OIG-0803-N
Room 5513, Cohen Building
330 Independence Avenue SW
Washington, DC 20201

Re: Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP

Dear Ms. Edwards:

On behalf of the Biotechnology Innovation Organization (BIO), we are pleased to submit the following comments related to OIG's Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP. BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than thirty other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics yield not only improved health outcomes, but also reduced health care expenditures due to fewer physician office visits, hospitalizations, and surgical interventions.

We are fortunate to live in a time of incredible advances of medical innovation. Trends toward personalized medicine and gene therapy are transforming health care as we know it. Unfortunately, developing these transformative therapies is neither easy nor inexpensive. It now costs on average more than $2.6 billion to research and develop a drug, get approval, and bring it to market.[1] Only 5 out of every 5,000 compounds becomes suitable for preclinical testing, and only 12% of all drugs in clinical trials ever make it to patients.[2] These tremendous risks undertaken with only an inkling of the possibility to bear fruit. Fortunately, our market economy is set up in a way that incentivizes these risky undertakings with market-based and statutory rewards designed to promote continued innovation. Things like patents, regulatory exclusivities, and the ability to establish prices based upon product value and market dynamics that foster competition rather than price controls. All of these components drive investment in the biopharmaceutical space and help ensure continued advancement in treatments of some of society's rarest and most intractable diseases. Unfortunately, however, as the treatment, development, and payment

[1] DiMasi and Grabowski, "The Cost of Biopharmaceutical R&D: Is Biotech Different," (2007).

[2] http://www.phrma.org/advocacy/research-development/clinical-trials#overview

landscapes have evolved over the past 20 years, oversight and enforcement policies have lagged behind.

BIO's membership is made up of small and emerging companies. More than ninety percent (90%) of these companies have operated at a negative net income, often for a decade or more.[3] Seventy percent (70%) of the global pipeline in new medicines is attributable to small and emerging companies, eighty-four percent (84%) of which are for rare or orphan diseases.[4] The fact that the vast majority of these drugs are for rare or orphan diseases creates a quandary for the biopharmaceutical manufacturers, payers, and policymakers: How does the market balance the overall value a drug offers to patients against the cost that enables the producer to recoup its investment – particularly in a rare or orphan patient population? This conundrum is far from theoretical, value-based payment arrangements are among the most talked about topics within healthcare. More and more, private insurers, pharmacy benefit managers, and industry are entering into arrangements that tie reimbursement to outcomes or otherwise augment the traditional mechanism of buying and billing. These partnerships are leveraging the ability of technology to track outcomes, analyze data, and evaluate important markers and endpoints that help tell a more comprehensive story about the value of a particular drug to each individual patient. In short, the private marketplace is evolving to ensure new – lifesaving – therapies can efficiently reach the patients that need them while balancing the necessarily high prices required to ensure future innovations and recoup enormous development costs. Unfortunately, government payers are missing out on some of the most important alternative payment models because of aging fraud and abuse prohibitions that are unnecessarily restrictive and not serving their purpose in the context of value-based contracting arrangements.

The past several years have seen the approval of multiple cellular therapies (CAR-T) and the first wave of gene therapies in the US.[5,6] Perhaps what was as striking as the innovative therapies themselves, which treat areas of high unmet need, are the innovative approaches companies are pursuing to ensure that reimbursement for these treatments facilitates timely and appropriate patient access – from refunds if endpoints are not met to pay-over-time arrangements when treatments are otherwise dosed only once. These arrangements are representative of how the private market has found solutions to address healthcare costs.

BIO believes these innovative payment models, including value-based contracting, are an important component of future payment discussions. There is growing application of these arrangements in the private sector and significant interest in such arrangements on the governmental side, but as OIG is aware, outstanding questions regarding the Anti-Kickback statute have limited their use. To be sure, industry has had productive dialogue with OIG related to alternative payment arrangements and patient support. Many organizations and coalitions have provided OIG with proposed safe harbor language and empirical evidence outlining both the importance of these arrangements and demonstrating their ability to be regulated to minimize any inherent fraud and abuse concerns. The shared

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[3] Factset, BIO Industry Analysis, January 2016.

[4] BIO Industry Analysis, BioMedTracker, June 2016.

[5] See: US Food and Drug Administration News Release: FDA approval brings first gene therapy to the United States, August 30, 2017.

[6] See: US Food and Drug Administration News Release: FDA approves CAR-T cell therapy to treat adults with certain types of large B-cell lymphoma, October 18, 2017.

goal here is to save the government money while ensuring beneficiaries of government insurance have equal access to all medically necessary treatments. Moreover, in the Medicare space more so than probably any other patient sector, patients tend to be on needed chronic and/or life-saving medicines that have either no medical alternative or are required due to drug-drug interactions arising from multiple comorbidities. In short, many of these patients have no "choice" in the type and brand of the medicines they must be taking and, as such, innovative payment arrangements and/or beneficiary inducement concerns are less than in some other areas of healthcare payment.[7] With this in mind, aspects of alternative financing arrangements and other beneficiary programs that might enhance medication adherence in the Medicare space in particular should have lower risks of fraud and abuse.

Considering the foregoing, we very much appreciate OIG's renewed interest in this topic of Anti-Kickback and Beneficiary Inducement reform. While we had hoped this updated interest might have evolved to formal rulemaking, we nevertheless look forward to working with OIG with the hope that such formal process might be on the horizon. BIO and its partners have provided several past comments to OIG and to CMS more broadly outlining aspects of fraud and abuse reforms that are necessary to ensure innovative contracting and enhanced medication adherence in the Government-paid healthcare programs.[8] As this process further matures, we truly hope that OIG appreciates the need for meaningful action to clearly permit responsible innovative contracting arrangements, advance adherence support programs, and further facilitate appropriate and transparent programs that aid patients in accessing their necessary medicines.

Promoting Care Coordination and Value-Based Care

With respect to the RFI's query on promoting care coordination and value-based care, we believe this is one of the most important aspects of reform in the oversight of fraud and abuse rules. As mentioned above, OIG has in the past received public comments on value-based arrangements via its annual Solicitation of New Safe Harbors and Special Fraud Alerts. In fact, OIG outlines multiple components of these proposals in its April 2017 Semi-Annual Report to Congress.[9] We assert that the best path forward, one that permits public vetting and analysis, would be for OIG to issue a proposed rule incorproating these proposals on value-based arrangements. An APA-supported proposed rule is more likely than an RFI to vet public concern and evaluate weaknesses and strengths of potential reforms. In fact, OIG outlines 11 specific safe harbor proposals in the Appendix to its Semi-Annual report, with over half of those proposals in the space of value-based arrangements and related issues like data analytics; all of which could be packaged into a proposed rule for comment.

In this context, we urge OIG to explore value-based arrangements as a stand-alone safe harbor rather than amending existing safe harbors to shoe-horn value-based arrangements

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[7] Even in the commercial market, concerns about manufacturer assistance encouraging the use of branded products over generics is largely overblown. Recent analysis showed that patients using co-pay cards on branded products when a generic was available accounted for only 0.4% of weighted prescription volume in 2017. See: An Evaluation of Co-Pay Card Utilization in Brands After Generic Competitor Launch. IQVIA Institute for Human Data Science, February 2018.

[8] See e.g. https://www.regulations.gov/document?D=HHSIG-2018-0001-0005

[9] *See* April 1, 2017 to September 30, 2017 Semi-Annual Report to Congress, Appendix G.

within their scope.[10] At a minimum, we anticipate a proposed rule to incorporate aspects of arrangements that permit risk sharing, incorporate all costs associated with incorporating and executing these arrangements, and that acknowledge the necessity of collecting data from payors by manufacturers (and vice-versa) in order to track and confirm milestones necessary to carry out these value-based arrangements. The proposal should also consider OIG's stated goals in promulgating safe harbors to "permit individuals and entities to freely engage in business practices and arrangements that encourage competition, innovation, and economy."[11]

As these enforcement changes are further considered we wanted to highlight the fact that arrangements that satisfy an AKS exception or safe harbor are deemed compliant with the CMP, but not the reverse. We suggest that a proposed rule could deem care coordination activities or arrangements that comply with the beneficiary inducement CMP when value is provided to a patient/potential patient by a health care provider to likewise be compliant with the AKS when value is provided to a patient/potential patient by health care providers or by other parties such as pharmaceutical manufacturers. If the OIG chooses not to deem all arrangements that comply with beneficiary inducement CMP exceptions also compliant with the AKS, the OIG should evaluate "carrying over" the following: (1) the informal exception for *de minimis* value, (2) the exception for promoting access to care with a low risk of harm, and (3) the exception for unadvertised items or services offered for free or less than fair market value based on financial need determination.

As a particular example, a new safe harbor could permit care coordination services (or specified types of care coordination services, potentially including hardware and software tools that have no or low independent value) to be provided by third parties such as pharmaceutical manufacturers to federal health care program beneficiaries enrolled in Medicare/Medicaid/other managed care programs (or traditional Medicare/Medicaid coordinated care programs like PACE – Program for All-Inclusive Care for the Elderly) if: (1) care has already been ordered for the member by a health care provider (e.g., drug prescribed), (2) the managed care plan (or related government authority) reviews the services and approves their offer to its members (as not disruptive/consistent with plan's care coordination activities), (3) the third party discloses that third party is a representative of manufacturer/has financial interest in member's continued receipt of care, and (4) provision of services otherwise complies with applicable laws (such as the Health Insurance Portability and Accountability Act, HIPAA).

As another example, care coordination services for patients, including federal health care program beneficiaries, can be necessary to support a value-based care arrangement in which the pharmaceutical manufacturer participates. If an arrangement links the price of a product to performance of the product, as measured by enhanced patient outcomes or reduced costs associated with use of the product (e.g., reduced hospitalizations), a manufacturer needs assurance that the failure to achieve the performance metrics is not caused by poor medication adherence.[12] Support could be expressly permitted through a safe harbor if expressly included as part of the value-based arrangement that is otherwise

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[10] We do not mean to discount the reforms to the Discount and Personal Services safe harbors, among others, that might enhance manufacturer and supply-chain contracting innovation. We just believe that an additional, stand-alone, safe harbor on value-based contracting would be of utmost importance in this instance. The ability to innovate, however, and to allow for more flexible but otherwise compliant arrangements in general could further be enhanced via previously proposed updates to these other safe harbors.

[11] 56 Fed. Reg. 35983 (July 29, 1991).

[12] As discussed more fully below.

compliant with other safe harbors such as the discount or warranty safe harbors. For the safe harbor to be useful, CMS may need to acknowledge that value of any such support should not be taken into account in government price reporting.

Additionally, as part of any proposed rule in this area, examples of terms needing comprehensive definitions would include "care coordination services", "care coordinator" and "coordinated care". Such terms – to foster the government's aim of advancing care coordination and value-based care – require definitions that expressly encompass and contemplate the coordination of care by third parties such as pharmaceutical manufacturers; acknowledge that care coordination includes activities needed to ensure timely access to needed care and prevent interruptions in care; and recognize that care coordination may include administrative (rather than solely clinical) activities and hardware and software supporting the services including modern technologies such as health activity monitors, or "wearables".

Finally, with respect to OIG's question in Section III(1)(E) regarding approaches short of rulemaking, we applaud this consideration, yet feel that this particular issue really needs comprehensive clarification beyond what a guidance might provide. To be sure, OIG has been responsive to many company requests by acknowledging its views on certain value-based arrangement via the Advisory Option process. Nevertheless, there is an urgent need for a more formal, specific, and permanent solution to facilitate value-based contracting. The Advisory Option process, in our view, is a useful tool to clarify the bounds of existing safe harbors and to test new enforcement positions on a case-by-case basis, but it is too narrow a tool to facilitate what necessarily needs to be an industry-wide pattern change in contracting.

Beneficiary Engagement – Beneficiary Incentives

Incentives and programs designed to help beneficiaries access and afford their medicines are seemingly a hot topic of debate both within public programs and also more broadly. This is due mostly to increasing patient exposure to cost-sharing and, in many cases, coinsurance calculated in a way that does not share products discounts and rebates with the actual patient. At bottom is ensuring patients can access and can afford the medicines that their health care providers deem necessary for them. Therefore, given the current realities of the insurance marketplace, it makes sense for the system to evaluate options for patients to better adhere to and more easily access medicines at a less significant up-front cost. Furthermore, the success of (and value of) value-based payment arrangements can only be effective if patients are adherent to their medications – assuming they can access them in the first place. In this area, BIO has been working alongside Prescriptions for a Healthy America (PHA) on a draft safe harbor for patient adherence programs. In fact, we have met with OIG alongside the Partnership on this very topic and want to reassert our support of the Partnership's formal proposed safe harbor on patient adherence programs.[13]

Examining the role played by benefit design in medication adherence has become even more important as commercial health plans – and even government programs – shift more costs to patients in the form of higher cost-sharing. But seemingly minor changes in benefit design can have significant impacts on patient adherence to medication. A study of the commercially-insured found that 69% would abandon a prescription at the pharmacy if cost-sharing exceeded $250, in contrast to the 11% that would not fill the prescription if cost-

[13] https://static1.squarespace.com/static/589912df1b10e39bd04eb3ab/t/5b11914d03ce649ac6fee482/1527877967076/P4HA+Safe+Harbor+White+Paper+vWEB.pdf

sharing were $30 or less.[14] The authors also found that assistance provided by manufacturers in the form of co-pay cards reduced abandonment rates between 12 and 19 percentage points each year between 2014 and 2017.[15]

Despite these efforts, non-adherence remains a significant concern and driver of both higher healthcare spending and worse health outcomes. We note that studies indicate that failure to take medications as prescribed causes an estimated 125,000 unnecessary deaths per year. What is more, poor adherence accounts for up to 10 percent of all hospitalizations annually.[16] Non-adherence has been estimated to cost the US healthcare system between $100 billion and $298 billion annually in direct costs.[17] The evidence shows that increasing patient adherence will result in significant improvements in clinical outcomes and a reduction in healthcare spending.[18]

Moreover, in many payment and contracting arrangements, adherence is a condition which underpins the overall focus on patient outcomes. For example, several publicly disclosed agreements require adherence rates be maintained at certain benchmark levels for the payer to be eligible for certain outcomes-based rebates.[19] Because of the importance of adherence in measuring a drug's success or failure, protecting appropriate adherence arrangements is critical to the success of value-based arrangements.

As stated in the PHA submission, providers, payers, manufacturers, researchers, and other stakeholders need additional flexibility to determine what works best in developing and implementing adherence initiatives, and thus must be able to test new ideas without undue risk of criminal prosecution. While existing Anti-Kickback exceptions and safe harbors, such as the discount or personal services safe harbors, will protect many arrangements designed to improve adherence, there is currently nothing –either in the statutory exceptions or the regulatory safe harbors – that explicitly protects adherence arrangements meeting specified standards. The Anti-Kickback statute should not criminalize adherence arrangements, because those arrangements do not promote any particular type of healthcare intervention, but instead promote patient adherence to a physician's recommendations. Nevertheless, a safe harbor that removes Anti-Kickback uncertainties and encourages adherence support with suitable safeguards can yield substantial benefits for federal healthcare programs and their beneficiaries, both by improving health outcomes and by reducing healthcare costs through avoiding the need for costlier medical care.

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[14] Katie Devane, et al. Patient Affordability Part Two: Implications for Patient Behavior & Therapy Consumption. IQVIA Institute for Human Data Science. May 2018.

[15] Ibid.

[16] Meera Viswanathan, et al. Interventions to Improve Adherence to Self-administered Medications for Chronic Diseases in the United States: A Systematic Review, ANN INTERN MED. 2012;157(11):785-795

[17] Viswanathan M, et al., Medication Adherence Interventions: Comparative Effectiveness. Closing the Quality Gap: Revisiting the State of the Science, Evidence Report/Technology Assessment prepared for the Agency for Healthcare Research and Quality (Sept., 2012) at 3.

[18] The CBO estimates that a 1% increase in the number of prescriptions filled by Medicare beneficiaries causes Medicare spending on medical services to fall by roughly one-fifth of 1%. Congressional Budget Office. Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services (November 2012).

[19] Duke Margolis Center for Health Policy, *Developing a Path to Value-Based Payment,* Appendix A.*;* https://www.biopharmadive.com/news/adherence-value-based-deal-payment-patient-outcomes/442449/

Beneficiary Incentives – Cost-Sharing Obligations

This area of oversight blends well into OIG's further query in the RFI on Beneficiary Incentives. More specifically, adherence initiatives necessarily call-to-mind discussions of beneficiary cost-sharing, since one necessarily precedes the other. Cost-sharing in general – and cost-sharing for government beneficiaries, in particular – is intended to cause patients to evaluate the need for discretionary care, but, importantly, not to discourage necessary care. For patients with cancer or rare diseases, a body of research shows an increase in cost-sharing will have a significant impact on the patient's decision to purchase a drug; these patients must choose between either getting the prescribed treatment, or forgoing treatment altogether.[20] Treatments for these diseases are usually expensive, and it is rarely the case that prescribers and patients have the option of choosing more cost-effective treatments with lower copays. For specialty and orphan drugs, where more cost-effective alternative treatments typically don't exist, requiring patients to pay large copays or coinsurance will simply serve to delay or discourage necessary care.

In the commercial sector, the practice of waiving cost sharing obligations, or the use of manufacturer-sponsored programs to alleviate some cost sharing burdens by patients, have become commonplace. But within the government sector, providers, practitioners and Part D plans have been given only limited permission to reduce and/or eliminate cost-sharing obligations, with boundaries being drawn strictly by the OIG.[21] BIO recognizes that there are concerns regarding these cost-sharing programs with respect to patient steering and/or other fraud and abuse issues. And, as such, manufacturers and other sponsors expend considerable resources designing programs that ensure benefits do not go to public program participants. Nevertheless, it is important to remember that cost sharing is a real inhibition to many federal beneficiaries being able to access prescribed medicines. This is particularly true in programs like Medicare, where patients are often not free to "choose" their medicine; either because a competitor or generic does not yet exist, or simply because an individual's Part D plan has utilization controls in place that prevail regardless. In any event, we believe that more consideration should be paid to the real barriers faced by beneficiaries in managing their government-mandated cost-sharing obligations. As such, we would be interested in further exploring with OIG opportunities for comment on proposals specific to the cost-sharing issues facing beneficiaries in today's marketplace. The practical reality is that as patients become more exposed to up-front costs – via insurance designs – access will continue to suffer.

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[20] *See, e.g., J*alpa A. Doshi, Ph.D. et al., High Cost Sharing and Specialty Drug Initiation Under Medicare Part D: A Case Study in Patients with Newly Diagnosed Chronic Myeloid Leukemia, 24 (4 Suppl.) Am. J. of Managed Care S78, S82 (Mar. 2016), available at https://www.ncbi.nlm.nih.gov/pubmed/27270157.

[21] *See*, *e.g.,* 42 C.F.R. § 1003.110(1). Exception to beneficiary inducement CMP prohibition permits waivers of coinsurance and deductibles if: (1) not offered as part of any advertisement or solicitation, (2) no routine waivers, and (3) waiver after good faith determination of financial need or failure to collect despite reasonable collection efforts; *see also*, HHS OIG Correspondence, Hospital Discounts Offered to Patients Who Cannot Afford to Pay Their Hospital Bills (Feb. 2, 2004). Medicare cost-sharing amounts may be waived so long as: (1) waiver is not offered as part of any advertisement or solicitation, (2) the party offering the waiver does not routinely waive coinsurance or deductible amounts, and (3) the party waives the coinsurance and deductible amounts after determining in good faith that the individual is in financial need reasonable collection efforts have failed; *see also*, 65 Fed. Reg. 24400, 24408-09 (Apr. 20, 2000). OIG contemplates that waivers or other reductions in cost-sharing obligations would be permissible incentives under the preventative care exception to the beneficiary inducement CMP; *cf.* 1994 OIG Fraud Alert. Routine waiver of deductibles and copayments by charge-based providers, practitioners or suppliers is unlawful because it results in (1) false claims, (2) violations of the AKS, and (3) excessive utilization of items and services paid for by Medicare.

Similarly, independent charitable foundations represent a life-line for patients who are underinsured or otherwise unable to access necessary medications. Notwithstanding significant changes to the healthcare insurance landscape over the past decade, serious gaps in coverage persist throughout the United States. These gaps are particularly apparent when assessing access to drug coverage, where insurers are increasingly subjecting patients to high cost sharing with increasing out-of-pocket costs on drug spend without corresponding hospital or physician service spend increases. In effect, patients are sometimes penalized for receiving life-saving prescription medicines through their insurance design. Access to charitable foundation support to offset or otherwise fill the void in insurance coverage is critical for many Americans. But these charities cannot operate on an island; funding sources are critical and necessary to ensure robust access, particularly with respect to beneficiaries in public programs, who are otherwise barred from accessing any other type of copayment or coinsurance assistance. To date, OIG's guidance on this topic has developed through advisory opinions and program guidances, not formal safe harbors that would be more broadly applicable across the industry.

Particularly when evaluating charitable support programs through the lens of small emerging biotechnology companies, the state of the law and guidances is murky. Safe Harbors in this instance would provide more concrete guardrails for companies evaluating whether support of independent charitable foundations are appropriate in a given circumstance. Given the enforcement activity in this space over the past several years, which has been robust, it is possible that absent a substantive development in this area of law support for independent charities will dwindle. This benefits no one. In the broader context of this RFI, we urge OIG to relook at this component of enforcement and work with industry on more formal rules to guide practice in the future.

Thank you for the opportunity to comments on this request, we only hope that our next round of public input will occur in response to a formal rulemaking. Should you have any questions or comments, please do not hesitate to contact me at 202-962-6673.

Regards,

/s/

John A. Murphy, III
Deputy General Counsel for Health